A STUDY OF PHARMACEUTICAL RESEARCH & DEVELOPMENT POST-2005 'PRODUCT PATENT' REGIME IN INDIA

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BY
RAVINDRAN KUTTAN KANNINGAT
Registration No: 15112112

UNDER THE GUIDANCE OF
DR. D. HENRY BABU

DEPARTMENT OF MANAGEMENT
SHRI JAGDISH PRASAD JHABARMAL TIBREWALA UNIVERSITY, VIDYANAGARI, JHUNJHUNU, RAJASTHAN – 333001

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1	Title to Research Work	A Study of Pharmaceutical Research & Development Post-2005 Product Patent Regime in India
2	Name of Scholar	Ravindran Kuttan Kanningat
3	Subject	Management
4	Registration No.	15112112
5	Name of Guide	Dr. D. Henry Babu
6	Designation	Director
7	Guide Working Place	Sterling Institute of Management Studies, Nerul, Navi Mumbai, Maharashtra, India.

SHRI JAGDISH PRASAD JHABARMAL TIBREWALA UNIVERSITY,

VIDYANAGARI, JHUNJHUNU, RAJASTHAN

DECLARATION BY THE CANDIDATE

I declare that thesis entitled “A Study of Pharmaceutical Research & Development Post-2005 ‘Product Patent’ Regime in India” is my own work conducted under the supervision of Dr. D. Henry Babu, Department of Management, ShriJagdish Prasad JhabarmalTibrewala University, Vidyanagari, Jhunjhunu, Rajasthan.

Place: Rajasthan Signatureof candidate

Date:

SHRI JAGDISH PRASAD JHABARMAL TIBREWALA UNIVERSITY, VIDYANAGARI, JHUNJHUNU, RAJASTHAN

CERTIFICATE OF SUPERVISOR

This is to certify that work entitled “A Study of Pharmaceutical Research & Development Post-2005 ‘Product Patent’ Regime in India” is a piece of research work done by Mr. Ravindran Kuttan Kanningat under my supervision for degree of Doctor of Philosophy in Faculty of Management of JJT University, Jhunjhunu, Rajasthan, India. That the candidate has put attendance of more than 100 days with me

Signature of Supervisor

A STUDY OF PHARMACEUTICAL RESEARCH & DEVELOPMENT POST-2005 PRODUCT PATENT REGIME IN INDIA

"The Indian pharmaceutical industry should turn their attention to invent new drugs from molecule levels and each manufacturing unit should try to become invention centres, opined Dr APJ Abdul Kalam, former President of India".

Introduction

In any given economy, there are about 5 – 10 per cent of the population always rich. They can buy anything that they would liketo buy from anywhere in this planet.For instance, if an affluent person fall sick, he can avail the best medical treatment anywhere in the world irrespective of how much it costsbecause he can afford it (E.g. Indian Cricketer Yuvraj Singh, who underwent treatment for cancerous tumour at the Cancer Research Institute in Boston and Medicine Facilities in Indianapolis, Indiana in USA). However, this is not the case with a large majority of Indians, for whom,though the fundamental right to health isguaranteed (WHO, UDHR and ICESC)but not availabledue to monopoly of drug inventionsthrough patent protection. Pharmaceutical invention is risky, expensive and lengthywith high rate of failuredemandsevery possible protection to prevent it from copying in orderto recover the huge developmental cost.

Due to the existence of strong patent protection in pharmaceuticals, only a selected few is affordable to accesspatented drugs in the world.The high prices are favoured by governments in the western world as most inventions are from companies originated from western countries. It is these manufactures who pushed for a strong intellectual property rights to be followed by all member countries of WTO, which is affecting the issue of drug accessibility and affordability in the world particularly the developing and least developed nations. Whatever may be the situation, medicine should be available and affordable to all, no matter which corner of the globe one live in order to eliminate human sufferings from earth. That'sthe only way to make this world a safer and better place to co-existfor everyone.

Although there is reduction inthe world population without access to essential medicine from 37% to 30% in 1999, yet the number is quite high stood at around 2.1 billion(World Medicines Situation, WHO 2004 study)people without access to medicine. Among nations,Africa and India share the largest concentration of drug inaccessibility as per WHO study. India has roughly 65% of people living without access to essential medicine.

Global Pharmaceutical Industry

Pharmaceuticals are a significant industry in the world. It is so significant because they provide important health benefits to the humanity. The industry is primarily privately owned, highly capital and technology intensive. Industry is extremely regulated, have large expenditure outlay on research and development. The existence and growth of pharmaceutical industry solely depended on the extent of new molecules it discovers and sell in the market.

The world pharmaceutical industry is dominated with over a dozen multinational companies, they control for more than 40% of the pharmaceutical market. Almost all major pharmaceutical inventions belong to them. There are estimated to be about 50 major pharmaceutical companies with annual sales revenue of more than a billion US Dollar worldwide.

Indian Pharmaceutical Industry

India was an import-dependent nation for pharmaceuticals, dominated by multi-national drug companies. Drug prices in the country were among the highest in the world. With the introduction of Indian Process Patent Act, 1970, the pharmaceutical scenario in the country has undergone tremendous changes making India self-reliant in pharmaceutical production. Industry produces mainly generic versions of patented drugs from simple headache pills to sophisticated antibiotics and complex cardiac compounds indigenously. India exports its bulk drugs and formulations to more than 200 countries in the world.

Today, pharmaceutical is one of the front ranking science-based industries in India with sophisticated manufacturing technology, achieved revenue of US$ 25.16 (AceEquity 2013), ranks globally 3rd in terms of volume of production (10 per cent of the global share) and 14thlargest by value (1.5 per cent of global share). Industry has many of its units approved for

stringent quality by regulatory agencies such as USFDA, MCA (UK), TGA (Australia), MCC (South Africa).

In terms of employment, the pharmaceutical industry has crossed a direct employment of over 800,000 people in 2008. A further 2.5 million jobs are thought to be involved in the pre-and post-production sector as well. However, keeping in mind the long term growth prospect, the industry has a potential of providing 1.17 million jobs in 2012 to 1.90 million in 2018. Most of these requirements are from areas like production, QC, research, sales, marketing and other support functions.

However in 1995, with India's acceptance of WTO led Trade Related aspects of Intellectual Property Rights (TRIPS) agreement, pharmaceutical companies had to resort to R&D of new drugs for survival and growth as they cannot anymore produce and sell cost effective generic version of patented drugs.However, the industry's response to new drug R&D has been pretty slow due to various reasons and the important being financial capacityto sustain long term research initiatives.

Research & Development (R&D)

A research can be defined as a process of scientific approach to discovering pertinent information on a specific topic.It is a creative work of an individual or a group to increase the existing stock of knowledge, which includes knowledge of man, his culture and the societyso as to improve and devise new applications. Research is an important contributing factor to the development of new technology and plays a crucial role in nation's economic progress. R&D is generally undertaken by the industry, academia as well as the government institutions.

Pharmaceutical research and development (R&D) refers to the discovery of either a new drug molecule or development of existing molecules or processes for the effective treatment of diseases. In short,researchers concentrateondeveloping New Chemical Entities (NCEs), Novel Drug Delivery Systems (NDDS) or generic drugsthrough reverse process engineering, which promise new hopes in the existing or new treatments.

Research and development is regarded as the backbone of the pharmaceutical industry. It is these new discoveries make the industry survive and grow. Therefore, the focus must be on discovery of new drugs to keep pace with the rising pattern of diseases in the world.

Indian Pharmaceutical Research & Development

Indian predominantly is a generic drug manufacturing country. Pharmaceutical companies rarely engaged in development-led research in drug molecules. Researchersin pharmaceutical companies haveconcentratedmainly on developing generic version of original patented drugs, Drug Master File (DMF), Abbreviated New Drug Application (ANDA),and Novel Drug Delivery Systems (NDDS) etc., because this generally do not require any pre-clinical and clinical study to establish safety and efficacy and are only required to demonstrate the bioequivalence of the product. Since 1947 Indian pharmaceutical R&D has developed only 17 new drugs, but none of this could find commercial success (Chaudhuri 2010).

Secondly, the process of drug development is expensive and lengthyand it doesn't always guarantee success too. Besides this, companies do not have adequate financial resources for long term research commitment. Indian companies spend less than 2% of their sales turnover on R&D as compared to their global counterpart 15% (Reji K. Joseph. 2010). The reason attributed to this situation may be due to India's recognition of 1970 process patent protection, which allowed companiesto reverse engineer the chemical process to develop generic version of patented drugs. India not only is an expert in the field of reverse process engineering but also highly successful in developing generic version of original drugs.

But, India's accession to Trade Related aspects of Intellectual Property Rights (TRIPS) in 1995 has changed the pharmaceutical scenario in the country. TRIPS agreement has virtually sealedIndia from producing patented drugs with reverse engineering technology. This has compelled pharmaceutical industry to focus on newdrug discoveryfor survival and growth.

Pharmaceutical industry has currently 270 R&D based organizations which include private and public sector companies and MNCs. Ranbaxy, Reddy's, Sun Pharma, Cipla and Lupin Labs lead the pack among leading Indian pharmaceutical companies. They have made a combined R&D

spending of US$356 million, which is approximately 8 to 10% of their earnings during the year 2008-09, which indicate a positive trend but not adequate enough to bring out new drug candidates. It is in this context, demands further studies to understand the dynamism of pharmaceutical R&D in the country.

Patents

Apatent is an exclusive right or a title granted to an inventor by a state authority, which exclude others from making, using or selling an invention. An invention may be about a new products or processes or significant improvements of an existing ones.Virtually all governments grant patents. A patent is granted for a specific period of time after careful examination of its genuinenessby trained inspectors. In case of drug, it is 20 years from the date of filing a patent. During the patent period the drug enjoys complete monopoly in the market, which allows the inventor firms to quickly recover thecost of developing the drug.

Pharmaceutical Patent

Pharmaceutical inventions as medical products and treatment involve a large degree of ambiguity as to what a scientific theory or discovery is, and to what extent to which a new medicine, or a new biologically engineered product is or is not independent of the underlying chemical and biological model that explains it. It is through this ambiguity coupled with lengthy and expensive nature of drug development, medical products and treatments have been increasingly patented in the world.

In pharmaceuticals, there are two distinct types of patent available: (i) the product patent, by which a drug is produced and (ii) the process patent, through which the chemical formula for the drug is engineered.

Product Patent: in which the product as well as the process of manufacturing the product is entirely patented. Companies can no longer employ methods of reverse engineering the chemical process to manufacture patent drugs.

Process Patent: in this case, only the process of manufacture of substances are patented, not the substances themselves i.e. the method of making the product is patented and not the product itself.

Indian Patent Act, 1911

Indian Patent Act, 1911 is a British inherited Indian Patent and Design Act. This act recognized both product and process patents for pharmaceuticals, and granted 14 years of exclusivity to new inventions.

Indian Patent Act 1970

Indian Patent Act, 1970 has replaced the Patent and Designs Act, 1911, abolishing all previous legislations including patent protection for pharmaceutical products to make way clear for affordable drugs to Indian public.The 1970 act played a significant role in the development of Indian pharmaceutical industry until 1995. The 1970 act had amended in 1995, 2000 and 2005 respectively to meet TRIPS compliance.

Indian Patent Amendment Act 2005

In keeping with the TRIPS commitments, India has carried out three important amendments to its existing patent laws of 1970 during the period between 1995 and 2005 to make India fully TRIPS compliant, which mandated product patent protection for pharmaceutical inventions.

Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

India signed TRIPS agreement on 15th April 1994, negotiated under the establishment of World Trade Organization (WTO), earlier known as General Agreement on Tariffs and Trade (GATT). TRIPS Agreement stipulates all WTO member countries to observe strong patent protection for 'Product' as well as 'Process' in pharmaceutical invention. TRIPS agreement also mandates a minimum patent term of 20 years from the date an application is filed.

Literature Reviews

1 **SubbaRaoChanganti(2008)**, states in his book, "**Pharmaceutical Marketing in India**", that the country is spending as less as 1.9 per cent of sales on R&D as compared to 10 – 20 per cent spent by pharmaceutical companies in the developed world. The book claims that the reason for such low R&D funding by Indian companies were due to low profitability. He further maintains that there is an abysmally low record of drug discovery in India; also the earliest drug discovered in India was the public sector undertaking. Therefore, he wonders why is it that in forty years the Indian pharmaceutical industry could not introduce a handful of commercially successful new drugs.

2 **Suresh Koshy (1995),** in hisBoston University paper, **The Effect of TRIPS on Indian Patent Law: "A Pharmaceutical Industry Perspective"** explains the importance of patent compliance with TRIPS and how it affects Indian pharmaceutical industry. He was of the opinion that the industry should have used the provision of ten year grace period effectively with active assistance from the government of India to prepare them ready and competent with the rest of the world. Government should have helped the industry with various fiscal and monetary incentives to make strong R&D before the actual implementation of TRIPS in 2005. The paper further discuss about creating an atmosphere of reformed patent laws and relaxed drug control regulations for companies to cap prices for new drug research that ensures a steady supply of new medications to consumers and highlighted the example of Japan's technological development and patent reform.

3 **Jean O. Lanjouw (1997),** in the Yale Universitydiscussion paper, **The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"** claims India won't be benefitted much by introducing product patent because; in India the drug accessibility is an issue to almost 70 per cent or so of its population. Therefore, he feels the inventor company may prompt to be discouraged in introducing new drug at low price in the initial years despite patent protection. As discussed in the paper, the benefit of patent protection will be possible provided there is enough R&D is done to develop drug therapies for the set of diseases which are relevant to Indian consumers, which according to him is done very little. The paper further discuss that India may not benefit

even in R&D investments by MNC as he feels a strong intellectual property rights alone will not compel MNC to relocate R&D in India.

4 **SanjeeveChandran et al. (2005),** in their paper, **Implication of New Patent Regime on Indian Pharmaceutical Industry: "Challenges and Opportunities"** argues that the absence of strong patent protection and encouraging reverse chemical process engineering for molecules already invented is responsible for poor R&D orientation, lack of professional expertise in new chemical entity development and lesser exposure to conducting advanced clinical trials by pharmaceutical industry in the country. The report further claims that there was very little or no effort was invested in the original drug discovery research leading to new drug molecules. It also maintains that more 90 per cent companies in India do not have sufficient capital or technology to initiate new drug research. Irrespective of the fact that the report suggests the edge exists for Indian pharmaceutical companies only if they are into continuous process of innovation and introduction of new drug molecules.

5 **SudipChaudhari (2005)**, in his IIMC, working paper, "**TRIPS and Changes in Pharmaceutical Patent Regime in India"**, describes TRIPS wasn't a natural acceptance in the parliament but a forced presidential decree, this reflects the opposition to product patent in India. It is said that product patent benefits only the inventor company, for example the exorbitant cost of AIDS drugs (US$ 10,000/ year), however, the price later crashed to US$ 350 to US$ 201/year only after due intervention from companies in India, which followed only process patent. The report further examines that the provision of compulsory licensing, which strike a balance between the private rights of patentees and the socio-economic needs and objectives of its people. However, its interpretation is so unclear provides opportunities for patentees to manipulate the process by litigation to prevent others from getting such licenses.

6 DwijenRangnekar (2005), in his University of Warwick working paper, **No Pills for Poor People? "Understanding the Disembowelment of India's Patent Regime"** discussed about the positive side of accepting the product patent as Indian companies can fully exploit the export market for their future growth because the domestic market has its own limitation

with respect to India's relatively low per capita income, limited access to medicine and negligible insurance coverage. Indian companies can capitalize on their strength to get USFDA approval for ANDA of generic drugs, strategic alliances with foreign firms, technology transfers, and enter areas of shared research, overseas production and global marketing.

7 **SudipChaudhuri (2007)**, in his IIMC working paper, "**Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS"**,shows the R&D expenditure around when TRIPS came into effect have gone up in Indian companies not only for the development of new process but for new chemical entities as well. However, argues that the incentive to do R&D is not primarily due to the anticipated product patent in India. He claims, for that matter, the product patent regime have not made much difference to developed countries in terms of R&D investments. The report further claims that the increased R&D investments yet to prove competence in innovating new products.

8 **Gopakumar G Nair (2008),** in his journal, **"Impact of TRIPS on Indian Pharmaceutical Industry"** views taking India to the global patent arena with re-introduction of product patent was the major contribution to TRIPS. Gives detailed account of various patent amendment acts culminating to IPA 2005. He believes that TRIPS agreement was a boon to Indian pharmaceutical industry as it had given from pre-TRIPS complacency to a sense of direction and urgency with regard to setting up world-class research facilities, initiation of New Drug Delivery System and introduction of new molecule research. He feels the post-TRIPS era has boosted pharmaceutical exports substantially not only to LDC but developed countries such as US and Europe. The report further says that the environment of the intellectual property right (IPR) knowledge has strengthened considerably in India.

9 **Ravi Kiran**and**Sunita Mishra (2009)**, in their international paper, "**Changing Pragmatics of the Indian Pharmaceutical Industry in the Pre and Post TRIPS period**" highlights the fact that, with the reintroduction of product patents, many Indian pharmaceutical companies have recognized the importance of R&D investments and discovery of new chemical entities.

This has prompted many companies to increase their R&D expenditures, which has touched a growth of 5.07 per cent from 3.88 per cent pre-TRIPS period. The study further reveals a strong relationship between increase in size of the firm lead to increase in R&D activities as well as R&D performance. The study has also found that there is a shift in better technology in pharmaceutical industry in India to suit the changing global scenario.

10 **Ravi Kiran**and**Sunita Mishra (2009),** in their international research paper, **Performance of the Indian Pharmaceutical Industry in Post-TRIPS period: "A Firm level Analysis"** observes the increase in R&D spending has brought drastic shift in the structure of R&D activities of Indian companies not only for new drug discovery but for developing capabilities to assimilate and exploit knowledge available externally. Indian firms are also able to tackle complex chemical synthesis relatively in a short period of time with cost efficiency. The paper further acknowledges the fact that post-TRIPS R&D focus by Indian pharmaceutical companies has indeed made tremendous increase in patent filing with respect to Drug Master Files (DMF) and Abbreviated New Drug Application (ANDA) with USFDA. Overall the post-TRIPS period saw the strongest performance of Indian pharmaceutical industry on several fronts.

11 **NeetuDubey et al. (2011)**, in their paper, **Performance of the Indian Pharmaceutical Industry Pre and Post TRIPS Era: "A Study**" provides a detailed account of pre-TRIPS and post-TRIPS scenario of Indian pharmaceutical industry. They are of the opinion that the Indian government has shown undue haste in signing TRIPS agreement without understanding many impending issues. The TRIPS agreement also failed to introduce R&D in the neglected disease and the diseases which are region specific. Their study of OECD countries shows the patent protection for pharmaceutical products was introduced after reaching their GDP per capita income at a sufficiently high rate. The paper accepts India's competency in chemical synthesis skill and the science of producing drugs cheaply. But in the long-run, under product patent, will bring price competition in the global generic drug market resulting wafer thin margins for the producers and suggests new drug molecules discovery to drive revenues and profits for the firm.

12 **Ravi Kiran**and**Sunita Mishra (2011)**, in his journal, "**Research and Development, Exports and Patenting in the Indian Pharmaceutical industry: A Post TRIPS Analysis"** examines the Impact of TRIPS on Indian pharmaceutical industry with respect to R&D, exports and patenting activity. The result of their study finds an increase in R & D expenses, and R&D intensity of leading pharmaceutical companies in the post-TRIPS scenario in India. This in turn has increased the number of regulatory filing such as Drug Master Filings (DMF) and abbreviated New Drug Applications (ANDA), which enable them to exports drugs in the regulated market such as the US and Europe.

13 **SubhajitBanerji**and**AnaghSengupta (2012)**, in their article, "**The Effect of the Indian Patents (2005) Amendment of the Pharmaceutical Industry and Access to Medicines in India"** gives a detailed account of the challenges faced following the sign up of TRIPS agreement by India. The paper discusses about the changed patent acts applicability in the context of patent rights versus human rights to access to medicines. They fear whether the provision of Compulsory Licensing will do the balancing act between the rights of the patent holder *vis-à-vis* the fundamental rights to health of its billion plus people as enshrined in the Constitution of India? Their apprehension compounded with the fact of the stark reality of poor research and developmental activity in India even after knowing the TRIPS regulation since 1995.

14 **MrinmoiChatterjee (2012)**, in "**Law on Pharmaceutical Patents"** gives a detailed accounts of laws relating to the pharmaceutical patents pre and post 2005 including patent laws practiced in other countries like US, Europe and Japan. The paper strongly suggests the patent should go well together with the public health policies and it should not distort competition that leads to reduced access and affordability of medicines to the poor mass of the country. The paper further substantiates its views by analysing Novartis Glivec case with respect to rationality of patenting and pricing of medicines, which according to her leaving the poor vulnerable. India's pharmaceutical companies must get into the act of path-breaking research and development in case the country wants to solve the problem of drug accessibility and affordability.

15 **Prashant B. Kalaskar**and **P.N. Sagar (2012)**, the authors in their review article, **Product Patent Regime Posed Indian Pharma Companies to Change Their Marketing Strategies: "A Systematic Review"** discusses about the possible strategies that can be designed by Indian pharmaceutical companies to meet new challenges posed by the product patent regime in order to remain competitive and profitable. They strongly recommended industry to invest on R&D of new molecules, devise unique R&D models to decrease cost and risk and continuously introduce new products to develop new competencies and sustain the momentum of growth. The authors in this paper strongly feel India, with its 40% cost advantage, should approach to MNCs for collaborative research to increase technological capabilities and economic development. The authors conclude their study by saying that investing in R&D and introducing newer molecules is the most preferred marketing strategy, however, companies should pay efforts in development of molecules that treat neglected therapeutic diseases specific to tropical regions like India.

16 **Boldrin& Levine (2013)**, in their research paper "**The Case Against Patents"** reveals that there is no empirical evidence to suggest that strengthening patent regime has brought in more social good to the general public, other than benefiting the corporate who patented the products. On the contrary, they claim in their study that the historical and international evidence suggests weak patent systems increased innovation with limited side effects, whereas strong patent systems retarded innovation with many negative side effects. They further defend in their paper that the eruption of innovations seldom, if ever, born out of patent protection and is instead the fruit of a competitive environment. Hence, a strong patent regime only increases patenting not innovation. Therefore they strongly suggest reforming the patent system with a well-designed and well-administered patent system that could spur innovation and social good.

17 **GehlSampath (2004)**, in his WHO study, **Economic Aspects of Access to Medicines after 2005: "Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry"** observes the implementation of TRIPS agreement will have direct implication not only to India but to a large number of least developed countries for access and affordability of medicines due to non-viability of compulsory licensing as a

supply mechanism, which makes little economic sense for Indian generic suppliers. His study gives a new dimension to the patent challenge and views Indian pharmaceutical companies will consolidate among them to face the patent challenge for its ultimate survival. The study further provides an analysis of the factors responsible for Indian firm's innovation strategies to emphasize on global diseases instead of being diseases specific to India is (i) the lucrative export demand of drugs that assures maximum return (ii) Indian firms fully fund their own research activities through their profits with little or no support from government.

18 **BiswajitDhar and K.M. Gopakumar (2006)**, in WTO study paper, "**Effect of Product Patents on the Indian Pharmaceutical Industry"** finds that new drug development is a perennial weak area of the Indian pharmaceutical industry; it requires major efforts from leading Indian firms in addition to increased efforts through government participation in the R&D investments. The reports stats that the government has not paid enough attention to it, instead through its appointed committee (Pharmaceutical Research and Development Committee (PRDC), had recommended only R&D collaboration between the Government-owned research laboratories (mostly under the Council of Scientific and Industrial Research) and the industry to engage in new drug discovery process. The study further analysed the likely impact of the new product patent regime and suggested industry to adopt radically different strategies with emphasis on strong technology generation in the area of new product research and development under new regime for survival. The report also made strong observation that TRIPS-determined patent system would not do as good as the 1970 Indian process patent act; accordingly the authors have suggested designing provisions that relate to patentable subject matter and compulsory licences to provide a level playing field. The study further exudes the confidence in Indian pharmaceutical industry to overcome the challenge once sufficient experience is gained from implementing the new regime. The authors in their concluding remarks have suggested a legal regime for preventing misuse of patent monopoly and also noted the TRIPS-consistent patent laws must strike a balance of rights and obligations. However, they say that objective of access to medicines at affordable prices to the mankind would be beyond the scope of patent legislation.

19 **BiswajitDhar and KM Gopakumar (2007)**, in UNCTAD projects, **Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: "The case of the generic pharmaceutical industry in India"** states that the TRIPS agreement has not dealt adequately the implication on health services of not only the developing nation like India but the least developed countries (LDC) as well. Many of the LDCs do not have manufacturing facilities as they have to be contingent up on the facilities of counties like India or other generic manufacturers in the world for easy supply of medicines. Though TRIPS agreement has a provision of compulsory licensing to facilitate drug access to latest drugs even under patent protection, but this facility will be effectively diluted with the introduction of "data exclusivity regime" clause provided in the Article 39.3 of the TRIPS Agreement, which requires member countries to protect undisclosed test or other data against unfair commercial use when such data are submitted for seeking marketing approval for products using new chemical entities. They further states that, these steps are clearly intended to extend the protection that a product would enjoy under the patent laws, thus rendering ineffective the process apart from maintaining a stranglehold over the markets for pharmaceutical products resulting in lack of drug access and affordability across LDCs and other developing world. The authors further declare that this clause would be a death knell for the generic industry in India. Their report further praised Indian pharmaceutical industry showing considerable dynamism on the R&D intensity and R&D investments, which have opened the doors for collaboration with pioneer producers. However, this has not yet borne fruits in terms of new drug discovery in the country, for which they suggests active government participation in the R&D activities involving the industry.

20 **Shashi Sharma (2007)**, in report, **New Patent Regime in India: "Challenges and Future of the Pharmaceutical industry"** represents his views that implementation of product patent protection will, in fact, improve Indian pharmaceutical industry considerably because, a strong patent protection is something what the global pharmaceutical giants are looking forward to enter Indian markets through various business contracts and collaborations with Indian companies in the area of pharmaceutical products manufacturing and drug research and development. The author confirms in his view that India has the required infrastructure, proven ability, skills and ample resources to undertake any major works that meet the global

demand for quality pharmaceuticals at affordable cost. The author further states that USFDA is willing to extend their help to Indian industry with their knowledge and expertise in order to transform the country a global hub for research and manufacturing activities. The author concludes his study with a remark that the Indian legal environment does lack the desired conviction to attract MNCs. A case in point is Novartis Gleevec litigation for patent protection that they lost in the Indian Supreme Court.

21 **SudipChaudhuri et al. (2010)**, in a study for UNDP, **Five Years into the Product Patent Regime: "India's Response"** has had an extensive study focussed on India's ability to maintain quality generic medicines at affordable price not only in India but across the developing world under the new patent regime. Though the capacity and capability of Indian generic companies to manufacture drugs has not yet weakened, but it is evident from their study that the implementation of TRIPS regime has adversely affected the opportunity to manufacture new patent drugs leading to idle capacity utilization. This has made drug less accessible and more expensive to the entire developing world. Their study further questions the wisdom and justification of the developing countries' grant of product patent protection in pharmaceuticals. The authors then suggests that governments, through their public sector units, should use all available options without violating TRIPS to improve access to essential medicines at affordable prices. They further guides us that Indian patent law contains robust safeguards, if strictly interpreted and applied, have the potential to eliminate a significant amount of patent barriers to affordable generic production.

22 **Reji K Joseph (2011)**, in his discussion paper, "**The R&D Scenario in Indian Pharmaceutical Industry"** provides a comprehensive analysis of the R&D expenditure and the R&D strategies of some of the leading Indian pharmaceutical companies post implementation of TRIPS regime in India. It was expected after TRIPS, Indian firms and MNCs would invest in R&D, increase technology collaborations and improve competence building for diseases not only prevalent globally but also specific to India and other tropical countries. The author, however, states that this was not the case in reality, and reveals that some leading Indian firms, in fact, have initially invested in new molecule research during 2000 – 01, but the growth has either declined or stagnated after 2005 – 06 due to many

reasons. India, therefore, did not progress in any such things like foreign investment, technology, competency or new molecule research focussing local diseases such as TB, malaria etc., after implementing product patent. The author further claims that due to lack of capacity of Indian firms both in terms of science & technology skills and financial resources led to the failure in developing new drugs. Author suggests, as the private sector industry is staying away, India must revive its public sector companies, which in the earlier policy regime have played a leading role, for indigenous innovations especially for the neglected diseases.

23 **Dennis B. Worthen, (2003)**, in pharmaceutical research paper, **American Pharmaceutical Patents: "From a Historical Perspective"** provides an historical perspective of the American patent laws with respect to pharmaceuticals ever since 1790. He is of a strong view that favours pharmaceuticals patenting and stoutly defended substantiating that the way to find new cures and treatments for diseases is only through research and innovation and innovation without adequate incentive has no guarantee for success and the mankind is losers of longer and healthier life. His study further reveals that the process patent was prevalent in America before the product patent. It is the 19th century after the World War II the American pharmaceutical industry put into the realm of research for new products and the need to patent its discoveries. Later several provisions were included as recommended by various committees like Kefauver-Harris and Waxman-Hatch Act so that the patent monopoly is not misused at the same time accessibility and affordability of drug established.

24 **Carsten Fink (2001)**, in the World Bank study, "**How Stronger Patent Protection in India Might Affect the Behaviour or Transnational Pharmaceutical Industries"** explains that a strong patent protection in developing countries do adversely impact their pharmaceutical industry through market structure and competition. It also affects the consumer welfare by way of drug access and affordability to the poor section of the society. However, the author strongly believes, in economic terms, that a new chemical entity unless legally protected by patents will easily be appropriated by the competing firms losing the first mover advantage to the innovator. Therefore, he maintains that the protection of patent right is considered to be a critical precondition for private investment in pharmaceutical research and the

development of new drugs. The author further maintains that, in the long run, there is possibility transnational companies will do more research on tropical diseases given that most developing countries moves towards stronger patent rights. The study further finds that a strong patent protection may induce the Indian government to impose price control or grant compulsory licenses.

25 **ShejaEhtesham and NiranjanMansingh (2008)**, in their commentary, **Conflicting Interest in Drug Pricing: "Innovation v/s Social Needs"** focusses on two sections of the society in an economy whose conflicting interests are explored. First, the pharmaceutical organization, who, through their intellectual property rights act trying to ensure protection to their inventions as monopoly rights to charge and recover the huge cost of drug research and development. On the other side, developing economy where the government as WTO members' have international obligation to protect peoples' right to health by providing accessibility and affordability of drugs recognized as important components of right to health. The authors asserts in their study that the net result of the TRIPS accord has turn out to be high cost of medicines and the consequent denial of access to medicines by low-income groups across the globe, accordingly they proposes two crucial suggestions to resolve the conflict by (i) using the method of optimal pricing linked to the nation's GDP, (ii) let government set up drug research and development establishments with an objective to make affordable novel drugs to major infectious diseases prevalent in developing and least developed countries.

26 **Boldrin and Levine (2004)**, in their international issue, "**The Economics of Ideas and Intellectual Property"** makes an attempt to balance the effects of patent monopoly through economic prisms and suggest governments that the best would be to eliminate patents and copyrights altogether as the government grants of patent monopoly were widely used as a mechanism of revenue extraction particularly in the context of developing world today. They are of the opinion that monopoly does not encourage innovation but produces fewer and lower-quality goods at greater cost. Therefore, they recommend governments across the world to provide extra incentives for invention and creation through subsidies, prizes, or

monopoly regulated through mandatory licensing so as to make drug more accessible and affordable to the poor world.

27 **Juma C. (1999)**, in Harvard University discussion paper, **Intellectual Property Rights and Globalization: "Implications for Developing Countries"**brings out a pertinent point related to technological cooperation and advocates the developed nation to be considerate and incorporate the same in the TRIPS agreement. The author states that the enforcement of intellectual property rights should contribute to the promotion of technological innovation, transfer and dissemination of technology for the benefit of both produces and users in the context of social and economic welfare and to a balance of rights and obligations. The paper further discusses the most challenging issue of how to mobilize the world's stock of knowledge to address the developing nation's problems of technological innovation and global capital flows. The author shows us the way to solve the issue by entering into partnerships and implementing viable programs that address the concerns of the developing nations. The discussion further denotes the public interest issues such as health, nutrition and environmental conservation to be addressed through scientific and technological cooperation in accordance with the provisions of the TRIPS agreement.

28 **Bruche, G. (2011)**, in European journal, **Emerging Indian pharma multinationals: "latecomer strategies in a globalised high tech industry"**explores the possibilities whether Indian Pharmaceutical companies (IPC), labelled as the emerging multi nationals of the developing world, have real capabilities and internationalization to join in the league of global research-based pharmaceutical companies. The study identifies that IPCs global competitive position is quite elusive in the above contexts. The paper argues that IPCs are not a serious threat to global biggies and the competitive position of Indian companies will largely remain as a subordinate status. The author agrees that many companies have real potential to become important players in the international arena. But, the challenge for them, mostly being family owned, is to overcome the rigid mind-set from making short-term gains to a capability-creating strategic business model that is based on innovation in order to enter in the strategic group of integrated global research-based pharmaceutical companies. The

author further agrees that although there is a significant number of IPCs evolving into research-based players but their related capability building processes are still far away.

29 **AmitShovon Ray (2008)**, in this paper, **Learning and innovation in the Indian pharmaceutical industry: "the role of IPR and other policy interventions"** the author underscores India's excellent track record of pharmaceutical technology and production, yet companies in India have a long way to go to the global frontiers of cutting edge drug discovery research. It can achieve this only through sustained technological efforts and continued R&D. The author further states that, in the post reforms scenario, it is the R&D that will play the key role in maintaining a successful trajectory of growth and development of the Indian pharmaceutical industry. Therefore, the author recommends a level playing field for Indian pharmaceutical companies along with a protective IPR environment to compete with global players.

30 **Gopakumar and Santhosh (2012)**, in their article, "**An unhealthy future for the Indian pharmaceutical industry"**has studied the MNCs post-TRIPS behaviour in India and reports that the strong IPR regime has not helped the country either with FDI in R&D, technology transfer or product innovation for local needs as expected, whereas many companies had the mandate to develop local products have closed down their R&D operation in India. This was the case with MNCs during pre-TRIPS period as well wherein they have shown an almost complete aversion of technology transfer in bulk drug production in India. The author further claims in his report that MNCs are slowly taking control of the Indian pharmaceutical market through importation patented drugs and registration of new products with Indian Patent Office. The report also deals with the much bigger issue of acquisitions and strategic alliances by MNCs with Indian companies of high level of technological capability which, according to the author, has not only eliminate the access of affordable drugs in India but force Indian companies completely dependent on MNCs for meeting the country's drug needs in the long run. For example, when Daiichi took over Ranbaxy, withdrew immediately all the patent challenges against Pfizer's blockbuster cholesterol drug Lipitor. This kind of developments would result in the ultimate takeover of Indian market by MNCs to a pre-1970 era making all essential drugs out of reach of common man.

Objectives

1. To evaluate the evolution and growth of pharmaceutical industry with respect to new drug research and development post-2005 ‘product patent’ regime in India.
2. To study the R&D investments in India by Indian as well as MNCs for new drug research.
3. To understand the R&D capabilities of Indian pharmaceutical companies with respect to new drug developments.
4. To identify the R&D intensities of Indian pharmaceutical companies

Hypotheses

With the above stated objectives in mind the following research hypotheses have been formulated for the present study.

1. There is no significant R&D investment to promote new molecule research in India after 20 years into signing TRIPS agreement.
2. Indian pharma companies’ lack financial resources to invest large sums into new drug research.
3. The small size and operation of pharmaceutical companies are affecting their earning potentials for large R&D investments.
4. There has been no quality FDI into pharma R&D despite strong IPR regime in force.
5. Strong intellectual property regime has failed to result in transfer of technology and research skills.

The Scope of the Study

The study will focus mainly on Indian pharmaceutical companies’ efforts towards new drug research and development post-2005 product patent regime, the financial resources and research skill and technology. Study will identify pharmaceutical companies R&D capabilities, R&D investments and R&D intensity in the country. Research will also explore the supports extend by the Government of India towards creating a conducive research environment in the country.

Sources of Data

Primary Data Collection: The first time data will be collected through observation, interview and, questionnaire designed to meet research objectives.A questionnaire consists a list of questions pertaining to the study is prepared and pro-testing was managed on selecting samples of Pharmaceutical/Biotech companies and Clinical research organization including staff involved in drug research & development. Personal contacts have been established with pharmaceutical and clinical research personnel, and of contact through mailsto draw out information. Finally, the interviews were conducted to go into the details of the present study. The research personnel were interviewed to cross examine the R&D activities taking place and the R&D capabilities required regarding new drug development.

Secondary Data Collection:These data which already exists in the public domain, collected and analyzed by some earlier agency for its own use. The relevant information with respect to Indian pharmaceutical industry, its background as well as R&D activities was collected through secondary sources. The secondary data has been sourcedfrom the statistical information available through various agencies such as government departments, CDSCO, Indian Patent Office, ASSOCHAM, EXIM, CII, FICCI, IIFT, OPPI, IPA, USFDA, US PTO, WHO, UN, WTO, publications of statistical records of market research agenciesAceEquity, Moneycontrol.com, management consultants McKinsey, Deloitte, KPMG, PWC, E&Y, IMS Health, US, German and UK pharmaceutical industries. Also thesis on related topics, books, international journals, working papers, newspapers, trade magazines, and company websites are studied to get the secondary data.

Statement of the Research Problem

The present research "A Study of Indian Pharmaceutical Research & Development Post-2005 'Product Patent' Regime in India"

Sample Size

A sample size of 200 R&D Heads from Pharmaceutical/Biotech companies, of which large size (20), medium size (60) and small size (120),and 60 Clinical Research Associates who are working in Clinical Research Organizations operating within the country have taken for

sampling. The study being descriptive and qualitative in nature, the researcher has online/personally approached the respondents with the 'Questionnaire and Interview Guide' to get more reliable and effective response.

Sampling Techniques

Simple stratified random sampling and interview techniques have been used. In the present study researcher will use analysis of the primary and secondary data. The research survey is limited to the R&D activities of the selected companies. Around 200research head from pharmaceutical R&D and 60 research investigators from Clinical Research Organization are selected using random sample technique. There are many Indian as well as multinational pharmaceutical companies operating within the country. While selecting companies and the customers 'Lottery Method' was adopted. In this study sample statistical techniques will be used to ascertain desired results by way of data analysis.

Research Area

Indian pharmaceutical companies engaged in drug research and development located across the country. Similarly, Contract Research Organization (CROs) who conducts various clinical studies within India on behalf of Indian as well as MNCs. There are many MNCs who use the service of Indian contract research organizations for various clinical studies at different phases of drug development. Samples are taken from respective states and data will be collected through questionnaires directly by researcher and also through online.In this study sample statistical techniques will be used to ascertain desired results by way of data analysis.

Research Design

As the study deals with factors like R&D investments, R&D intensities and R&D capabilities of Indian companies with respect to new drug discovery and associated problems and to aid and suggest the government of India to actively invest in new drug discovery in the country. The research is based on direct personal investigation on these parameters. For this purpose two specific research instruments 'Questionnaire and Interview Guide' are used. The study is a survey in nature with both Qualitative and Quantitative approach. As a tool the study has used Questionnaire at a large and Interview

Guide at a small extent to collect more in-depth information about the issues related to discovery of new drugs by pharmaceutical companies in India.

Conclusion

Introduction of strong intellectual property right should not be considered as an evil, but it will do well only when industry attains certain level of competency with regards to finance, research skill and technology. New drug discovery is expensive, lengthy and high-risk, high-failure investment choice,for which adequate financial resources arerequired for firms to engage on a long term basis to become successful. Indian pharmaceutical companies are small in size, operation, revenue and profitability which are affecting their finance resulting poor R&D investments for new drug discovery initiatives. India lack in the critical area of medicinal chemistry skills and research technology to optimize molecular research in the country. Introduction of strong intellectual property regime has not attractedFDI and technology transfer to promote new molecule researchdespite 20 years into signing TRIPS agreement by the government of India.In this context, government must investment directly into new drug R&D to help solve the issue of drug accessibility and affordability. It will save not only the pharmaceutical industry, but millions of people from life and death.

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